IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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ARGUMENT

I. All of Plaintiff's Claims Fail Because Plaintiff Cannot Establish Cause in Fact

To raise a triable issue regarding cause in fact, Plaintiff would have to present evidence of (1) how much, if any, Neurontin Mr. Smith took, (2) when he took it, and (3) that he took it sufficiently close in time to his suicide to make a threshold showing of biological plausibility necessary to support causation. Plaintiff would also have to present evidence that a different warning to Mr. Smith's prescribing doctor would have changed that doctor's prescription decision. Plaintiff's failure to present any such evidence requires the entry of summary judgment as to all of her claims.

A. There Is No Competent Evidence That Mr. Smith Consumed Neurontin Shortly Before His Suicide

Plaintiff has presented no competent evidence that Mr. Smith ingested Neurontin at any time temporally related to his suicide. She argues that "Defendants' suggestion that Plaintiff must offer testimony of an eyewitness who saw Mr. Smith popping Neurontin into his mouth during the three days prior to his suicide is . . . unsupported by any authority." (Pl's Mem. Opp. Renewed Mot. Summ. J. [51] ("Pl. Opp.") at 5.) But this contorts and oversimplifies Pfizer's argument. Pfizer's opening brief provides ample authority for the settled and utterly uncontroversial principle that the plaintiff in a prescription drug products liability case must show that the injured person actually ingested the medication at issue. *See Porter v. Whitehall Labs., Inc.*, 791 F. Supp. 1335, 1340-41 (S.D. Ind. 1992), *aff'd*, 9 F.3d 607 (7th Cir. 1993); *Stanback v. Parke, Davis & Co.*, 502 F. Supp. 767, 771 (W.D. Va. 1980); *see also Barnes v. Kerr Corp.*, 418 F.3d 583, 589-90 (6th Cir. 2005) (affirming summary judgment to manufacturer where there was insufficient evidence that plaintiff was exposed to mercury from defendant's products). Pfizer also provided authority holding that the injured person must have ingested the drug at a time temporally related to the injury. *In re Propulsid Prods. Liab. Litig.*, 261 F. Supp. 2d 603, 608-09, 617-18 (E.D. La. 2003) (granting summary judgment where plaintiff stopped

taking drug prior to alleged injury and there was no competent evidence that drug could cause prolonged effects).

For her part, Plaintiff does not and cannot cite any contrary authority holding that plaintiffs do not have the burden to prove by competent evidence that the injured person actually took the defendant's drug at any time when it even arguably could have caused injury.[1]

The type of evidence of ingestion is not the issue; the utter lack of any such evidence is. Pfizer does not claim that "testimony of an eyewitness who saw [the patient] popping [the drug] into his mouth" is required in all cases. What is required is that Plaintiff present evidence of ingestion that is admissible under the federal rules of evidence or otherwise competent under Federal Rule of Civil Procedure ("FRCP") 56.[2] Here, there is no evidence of how many pills, if any, were missing from the only bottle of Neurontin Mr. Smith ever purchased – a bottle Plaintiff's own expert concedes "looks like it's full of Neurontin." (Maris Dep. [MDL 1644-4] at 527:24-528:1). There is no evidence that Mr. Smith took any of the samples of Neurontin given to him by Nurse Pamela Krancer. There is no evidence that Mr. Smith had any Neurontin

[1] As Plaintiff correctly notes, the *Best v. Lowe's Home Centers, Inc.* decision cited in Defendants' opening brief was amended on reconsideration and later reversed. *See* No. 04-cv-294, 2008 WL 2359986 (E.D. Tenn. June 5, 2008), *amended by* 2008 WL 2566526 (E.D. Tenn. June 24, 2008), *rev'd* 563 F.3d 171 (6th Cir. 2009). Defendants apologize to the Court and counsel for this oversight. But the basis for reversal was that the trial court "did not recognize that differential diagnosis is a valid technique that often underlies reliable medical-causation testimony" (though it does not necessarily meet *Daubert* standards in all cases). *Best*, 563 F.3d at 178. This holding does not purport to change plaintiffs' well-settled burden in cases like this one of presenting non-speculative evidence that the injured person actually ingested the subject drug during a time period when it plausibly could have caused the person's injury. Without such evidence, there would be no basis for expert causation testimony based on a differential diagnosis, because such diagnoses cannot "'rule in'" potential causes of injury that are not "'scientifically plausible.'" *See id.* at 180 (citations omitted). Moreover, Defendants' argument is not that mere "temporality is insufficient to establish causation" (Pl. Opp. at 5) – although it is insufficient, and the Sixth Circuit did not hold otherwise. Instead, Defendants' argument is that the *absence* of any temporal connection between consumption of a drug and the alleged injury *negates* causation. *See, e.g., Propulsid Prods. Liab. Litig.*, 261 F. Supp. 2d at 608-09, 617-18. (*See also* Defs. Mem. Supp. Summ. J. [18] ("Def. Mem.") at 7 n.1.)

[2] Except for the document categories specifically enumerated in FRCP 56, documents submitted on a summary judgment motion must be in a form that would be admissible at trial. *See, e.g., Duplantis v. Shell Offshore, Inc.*, 948 F.2d 187, 192 (5th Cir. 1991).

in his system at the time of his death. No one observed Mr. Smith taking Neurontin during the days prior to his death, or at any particular time. And Mr. Smith had an undisputed history of non-compliance with his doctors' instructions regarding Neurontin use.

Plaintiff offers various excuses for this lack of evidence. For example, Plaintiff argues that it "would certainly not be unusual" that no toxicology tests were performed. (Pl. Opp. at 6.) Likewise, regarding the fact that Mr. Smith's one and only Neurontin bottle looked "full," Plaintiff cites the medical/death investigator's testimony that he "probably" did not do a pill count. (*Id.* at 2.) But Plaintiff cannot survive summary judgment by simply making excuses for the lack of evidence and asking the Court to presume that, if such evidence existed, it would support her claim. Because Plaintiff has the burden of proving causation at trial, she must come forward with evidence of ingestion sufficient to raise a triable issue of fact. Rule 56 requires the nonmovant to "go beyond the pleadings" and, by admissible evidence, "designate 'specific facts showing that there is a genuine issue for trial.'" *Moore v. Philip Morris Cos.*, 8 F.3d 335, 339 (6th Cir. 1993) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986)).

Plaintiff also resorts to conclusory assertions and speculation – neither of which are sufficient to defeat Pfizer's motion. *See, e.g.*, *Bryant v. Kentucky*, 490 F.2d 1273, 1275 (6th Cir. 1974) (per curiam) (nonmovant cannot satisfy her burden through "[m]ere conclusory and unsupported allegations, rooted in speculation"); *Hodges v. R.M.S.I. Med. Dep't Nurses*, No. 07-0284, 2009 WL 981979, at *2 (M.D. Tenn. Apr. 13, 2009) (Trauger, J.) ("Conclusory allegations, speculation, and unsubstantiated assertions are not evidence and are not sufficient to defeat a well-supported motion for summary judgment.").

For example, it is undisputed that the only Neurontin samples found after Mr. Smith's death were in blister packs that "remained sealed." (Cindy Smith-Charlton Dep. [MDL 1679-22] at 14:21-22.) These blister packs, in turn, were kept in boxes that "appeared closed" prior to Mr. Smith's death.[3] (*Id.* at 81:16-83:10.) There is no evidence that any blister packs were ever found

[3] As of October 2, 2007, when Ms. Smith-Charlton was deposed, some of these boxes "have been opened." (*Id.* at 14:21.) But prior to Mr. Smith's suicide, they "appeared closed." (*Id.* at 83:10.)

outside of these "closed" boxes. (*Id.* at 83:3-6.) Plaintiff argues that this undisputed evidence "does not disprove" her speculative notion "that there were whole blister packs of Neurontin from which Mr. Smith had ingested the Neurontin." (Pl. Opp. at 6.) In other words, Plaintiff asks the Court to assume – without a shred of supporting evidence – that Mr. Smith was regularly taking Neurontin samples, that the last sample he took happened to come from the very last blister pack in one of his sample boxes, that he discarded all empty blister packs and all empty boxes, and that he did so long enough before committing suicide that no empty blister packs or boxes were ever found. While Plaintiff may be entitled to reasonable inferences supported by the evidence, she is not entitled to such an extended series of speculative inferences based on no evidence. *See, e.g., Moore*, 8 F.3d at 340 (nonmovant cannot satisfy her burden by pointing to "some metaphysical doubt as to the material facts"). Nor is Pfizer required to "disprove" such speculations. Where, as here, the non-moving party has the burden of proof to establish her claim, the movant "need not support its motion with affidavits or other materials '*negating*' the opponent's claim." *Moore*, 8 F.3d at 339 (quoting *Celotex Corp.*, 477 U.S. at 323).

In attempting to show that Mr. Smith took Neurontin during the days leading up to his suicide, Plaintiff primarily relies on her own testimony "that her husband took his medication in the way that the doctor had prescribed it, and that she knows this to be the case." (Pl. Opp. at 2.) But Plaintiff's testimony reveals that she has no such first-hand knowledge. Plaintiff "can't recall whether [she] observed [Mr. Smith taking Neurontin] every time" (Ruth Smith Dep. [MDL 1644-5] at 143:14-15), and does not even claim to have seen him take Neurontin at any particular time. She claims that "he usually kept it on the dinette table, and that's where he would take it." (*Id.* 143:15-16.) In fact, Mr. Smith's Neurontin bottle was found on his bedroom "dresser," not his dinette table. (Maris Dep. [MDL 1644-4] at 527:24-528:1.) But the issue is not where Mr. Smith kept his Neurontin, but whether he actually took it, and if so, when he last did so before committing suicide. Any assumption that Mr. Smith took Neurontin during the days leading up to his suicide is rank speculation based solely on Plaintiff's conclusory statement that "[t]hat was

just the way he did things." (*Id.* at 143:2-11.) Arguing that she "knows this to be the case" does not turn Plaintiff's speculations and conclusory statements into first-hand knowledge.

Indeed, Plaintiff's testimony is not just speculative, but flatly inconsistent with the record. It is undisputed that Mr. Smith was prescribed Neurontin over a year before his death, on May 5, 2003, but that he never even filled that prescription.[4] Thus, while Plaintiff bristles at the notion that Mr. Smith would have "***refused*** to take a pharmaceutical drug that had been specifically prescribed to treat his medical condition" (Pl. Opp. at 5), Mr. Smith had an established history of such non-compliance. The undisputed evidence further shows that Mr. Smith did not follow Dr. Mackey's instructions regarding his March 9, 2004, Neurontin prescription – the only such prescription Mr. Smith ever filled. Had he done so, he would have run out of pills by April 8, 2004, but the bottle appeared "full" at the time of his death more than a month later, on May 13, 2004. (Granacher Report [MDL 1644-12] at 6; Maris Dep. [MDL 1644-4] at 527:21-528:15, 540:5-18.) Likewise, and contrary to Plaintiff's speculations discussed above, there is no evidence that Mr. Smith took a single one of the Neurontin samples Nurse Krancer gave him. All of this undisputed evidence refutes Plaintiff's testimony by showing that, for Mr. Smith, taking prescription drugs according to his doctors' instructions "was [***not***] the way he did things." (Ruth Smith Dep. [MDL 1644-5] at 143:2-11.)[5]

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[4] (*See* Ruth Smith Dep. [MDL 1644-5] at 112:13-117:15; Maris Dep. [MDL 1644-4] at 536:11-537:20. Plaintiff admits that these facts are undisputed. Pl.'s Resp. to Defs. Local Rule 56.1 Statement of Undisputed Material Facts [1678] ¶¶ 1 & 2.)

[5] While Plaintiff does not even argue that her speculative, conclusory testimony could be admitted as evidence of "habit" under Federal Rule of Evidence ("FRE") 406, any such argument would have to be rejected. Particularly in light of Mr. Smith's undisputed history of non-compliance with his doctors' instructions, Plaintiff cannot make the required showing under FRE 406 "that 'the behavior at issue occurred with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances.'" *Bell v. Consol. Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio 2004) (citations omitted); *accord Osborne v. Pinsonneault*, No. 4:07-cv-002, 2009 WL 1046008, at *3 (W.D. Ky. Apr. 20, 2009). Even without this evidence of non-compliance, Plaintiff's "subjective and conclusory statements are insufficient to show" that Mr. Smith had a habit of taking prescription medication as directed. *Bell*, 299 F. Supp. 2d at 801. Moreover, Plaintiff's testimony is far too generic to describe a "habit" for purpose of FRE 406. A "habit" describes "a specific type of conduct, such as the habit of going down a particular stairway two stairs at a time, or of giving the hand-signal for a left turn, or of alighting from railway cars while they are moving." Fed. R. Evid. 406 advisory committee's note. *(cont'd)*

Plaintiff's remaining arguments are likewise deficient. Citing a non-existent "Ex[hibit] 31,"[6] Plaintiff claims that Mr. Smith told his physical therapist he was taking Neurontin on April 14, 2004. (Pl. Opp. at 2.) Plaintiff appears to have intended to reference Exhibit 30 [MDL 1679-31], which purports to be a physical therapy record listing Neurontin as a "current medication[]." Even assuming *arguendo* that this record could support an inference that Mr. Smith had actually taken Neurontin as of April 14, 2004, it is not evidence that he continued taking it as directed every day thereafter until May 13, 2004, or at any time temporally related to his death.

Plaintiff further relies on the deposition testimony of Mr. Smith's son-in-law, Lewis Wesley Carnahan II, regarding hearsay statements purportedly made by Mr. Smith on or about May 8, 2004, to the effect that he had taken Neurontin and that it had made him feel "loopy." (Pl. Opp. at 2 (citing Carnahan Dep. [MDL 1679-27]).) Mr. Carnahan's after-the-fact summary of what Mr. Smith may have said is pure hearsay not subject to any hearsay exception. Mr. Smith's purported statement that he was taking Neurontin is plainly being offered "to prove the truth of the matter asserted." *See* Fed. R. Evid. 801(c). And even assuming *arguendo* that the purported statement about "feeling loopy" could be admitted under FRE 803(3), any reference to Neurontin as a potential cause of that condition would be inadmissible.[7] [8]

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Plaintiff's testimony also violates FRE 404, which provides that a "trait of character is not admissible for the purpose of proving action in conformity therewith" except in narrowly prescribed circumstances not present here. Fed. R. Evid. 404(a).

[6] The declaration in question contains Exhibits 1-30; there is no Exhibit 31. (*See* Decl. of Finkelstein in Opp. to Defs' Mot. Summ. J. [MDL 1679].)

[7] FRE 803(3) applies to a declarant's "contemporaneous statements as to her state of mind – that she was afraid, hungry, exhausted." *United States v. Alzanki*, 54 F.3d 994, 1008 (1st Cir. 1995). The rule does not "allow more expansive statements elaborating upon the underlying reasons for the declarant's state of mind." *Id.* Otherwise, "any hearsay statement would be admissible if it were preceded by the statement, 'I am (insert state of mind) because X.' Such an interpretation would completely destroy the general prohibition against the admissibility of hearsay statements." *Daniels v. Lafler*, 192 F. App'x 408, 425 (6th Cir. 2006).

[8] Likewise, while Plaintiff has not even attempted to show that the purported hearsay statement to Mr. Carnahan could qualify for admission as a "[s]tatement made for purposes of diagnosis or treatment" under FRE 803(4), any such argument would have to be rejected. Though Plaintiff describes Mr. Carnahan as "***a*** pharmacist" (Pl. Opp. at 2 (emphasis added)), he was not ***Mr. Smith's*** pharmacist. Indeed,
(cont'd)

Finally, Plaintiff relies upon a May 19, 2004, letter written by Mr. Smith's dentist that recounts hearsay statements purportedly made by Mr. Smith more than a week earlier, on May 10, 2004. (*See* Pl. Opp. at 3 (citing 5/19/04 Letter from Dr. Wood [MDL 1679-2]).) According to the letter, Mr. Smith stated that Neurontin made him feel "weird" and was not "helping" him. On its face, the letter itself is inadmissible hearsay. Likewise, the purported statements described in the letter are also hearsay, and are inadmissible for the same reasons pertaining to the statements purportedly made to Mr. Carnahan.[9]

Beyond being inadmissible, Mr. Smith's purported statements to Mr. Carnahan and Dr. Wood did not indicate that he had actually taken Neurontin on the days he made those statements, nor are they evidence that he took Neurontin during any of the following days leading up to his death. If anything, the assertion that Mr. Smith, in a three-day period, complained to two different people that Neurontin made him feel strange and was not helping him undermines, rather than supports, Plaintiff's speculation that he continued taking it.

In sum, there is no competent evidence that Mr. Smith took Neurontin at any time temporally related to his death.

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Mr. Carnahan testified that until the purported conversation on or about May 8, 2004, he had no idea that Mr. Smith had been prescribed Neurontin. (*See* Carnahan Dep. [MDL 1679-27] at 19:18-21.) Thus, the hearsay statement did not pertain to any "diagnosis or treatment" rendered by Mr. Carnahan. Moreover, Pfizer is unaware of any authority – and Plaintiff cites none – applying FRE 803(4) to statements made to pharmacists, let alone statements made in an informal conversation with a relative, who happened to be a pharmacist, for purposes totally unrelated to filling prescriptions. Indeed, the presumption of reliability on which FRE 803(4) is based is plainly not present where, as here, the statement is proffered by an interested witness whose wife and mother-in-law would directly benefit from any jury award predicated on the proffered hearsay statement.

[9] Dr. Wood's letter [MDL 1679-2] states that Mr. Smith's "reason for coming" in that day related to his "gums." There is no indication that Mr. Smith was seeking "diagnosis or treatment" from his ***dentist*** for chronic back pain or side effects from medications purportedly taken for back pain. *See* Fed. R. Evid. 803(4).

B. There Is No Competent Evidence That Neurontin Has Prolonged Effects on Brain Chemistry

Plaintiff has failed to show that Mr. Smith took Neurontin sufficiently close in time to his suicide to make a threshold showing of biological plausibility necessary to support causation. As Plaintiff's expert Dr. Maris has conceded, the relevant time period for Mr. Smith's ingestion of Neurontin is narrow: Because Neurontin has a half life of 5 to 7 hours,[10] there would be no appreciable Neurontin left in an individual's system within twenty-four hours after taking the drug. (Maris Dep. [MDL 1644-4] at 549:24-550:16.) Dr. Maris further admits that there is not "any evidence" that Mr. Smith took Neurontin during any of the "four" days before he committed suicide, or "on any particular day." (*Id.* at 529:14-531:4.) This is fatal to Plaintiff's claims because there is no competent scientific evidence that Neurontin can have prolonged effects on a patient's brain chemistry after it has left the patient's system. *See Propulsid*, 261 F. Supp. 2d at 608-09, 617-18 (granting summary judgment where plaintiff stopped taking drug prior to alleged injury and there was no competent evidence that drug could cause prolonged effects on, *inter alia*, "neurotransmitter[s]").

Plaintiff argues that this case is somehow different from *Propulsid* because, instead of claiming long-term cardiac effects, she claims that the alleged "suicidogenic effects of Neurontin would still have been present in [Mr. Smith's] system" after he stopped taking the drug. (Pl. Opp. at 6.) This is a distinction without a difference. Whether the "effects" of a drug can endure after the patient has stopped taking it was the precise issue addressed in *Propulsid*. That court correctly held that competent expert evidence of such prolonged effects is required, and that absent such evidence, summary judgment is warranted. *Propulsid*, 261 F. Supp. 2d at 608-09, 617-18. Plaintiff cites no contrary authority.

As in *Propulsid*, Plaintiff has presented no competent evidence that Neurontin has prolonged effects on brain chemistry. Plaintiff claims that her experts' admissions regarding

[10] A medication's "half life" is the time it takes to be eliminated from blood plasma by one half of its strength. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 810 (30th ed. 2003) [MDL 1644-15].

Neurontin's 5-7 hour half-life only apply "to the amount of Neurontin in the blood/plasma and not to the amount of Neurontin in the brain." (Pl. Opp. at 6.) But Plaintiff has presented no evidence that Neurontin remains "in the brain" after leaving "the blood/plasma." Moreover, this argument fails to distinguish *Propulsid*, because the plaintiff in that case – like Plaintiff here – claimed without supporting evidence that there was a prolonged effect on "neurotransmitter[s]" after the drug left the system. *Propulsid*, 261 F. Supp. 2d at 608-09, 618.

Lacking any competent expert evidence, Plaintiff instead relies on Dr. Trimble's testimony that Neurontin could have a longer – but unspecified – half-life in elderly patients. (Pl. Opp. at 6.) But Dr. Trimble admits that he has "***no data*** to support [that] opinion," and while he speculates that such data "would be found in company documents," he has not even "looked for [any such] company documents." (Trimble Dep. (1/15/10 Cheffo Decl., Exh. 1) at 251:19-252:5 (emphasis added).) Likewise, Plaintiff argues, based on Dr. Trimble's testimony, "that if you have been taking Neurontin for two months, it would take several days at least after your last dose before there is no appreciable Neurontin in your system." (Pl. Opp. at 6.) Again, Dr. Trimble admitted that this "opinion" is based on pure speculation.

> Q. And on what would you base your opinion that it would be several days at least?
>
> A. On what I've just said, that the drug has to come out of the body tissue, body system. ***But that is a guess. As far as I know, it's not been looked at***.

(Trimble Dep. (1/15/10 Cheffo Decl., Exh. 1) at 259:7-12 (emphasis added).) Moreover, while Dr. Trimble was addressing the hypothetical situation of a patient who "ha[d] been taking [Neurontin] for two months (*id.* at 258:24-259:1), there is no evidence whatsoever that Mr. Smith took Neurontin for two months. *See* Section I.A, *supra*.

In attempting to rely on her experts' *ipse dixit* speculations, Plaintiff fundamentally misapprehends her burden as the proponent of expert evidence and as the party opposing summary judgment. Pfizer does not have the burden of "'*negating*'" Plaintiff's speculative notion that Neurontin can have a prolonged effect on neurotransmitters. *Moore*, 8 F.3d at 339 (citation omitted). Rather, Plaintiff has the burden of supporting that notion with competent,

reliable scientific evidence, and her failure to do so requires the entry of summary judgment. *See Propulsid*, 261 F. Supp. 2d at 618; *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1071-72 (6th Cir. 1993).

C. There Is No Competent Evidence That Mr. Smith Would Not Have Been Prescribed Neurontin Had a Suicide Warning Been Included on the Label

As shown in Pfizer's opening brief, there is no evidence that different or additional warnings would have changed Dr. Mackey's decision to prescribe Neurontin to Mr. Smith. (Def. Mem. at 12-15.) To the contrary, Dr. Mackey – an orthopedic surgeon who does not prescribe drugs for Neurontin's labeled indications – continues to prescribe Neurontin and "still will prescribe it" despite his awareness of the alleged suicidality risk. (Mackey Dep. (1/15/10 Cheffo Decl., Exh. 2) at 9:5, 19:11-25, 83:24-84:13.) He testified that if Mr. Smith had walked into his office in ***May 2007***, he would have prescribed Lyrica – another AED medication with alleged suicidality risks, which was not available during the relevant time period. (*Id.* at 92:16-93:2.) But even though he was repeatedly and specifically asked (*see id.* at 43:1-3, 92:16-20), Dr. Mackey never testified that different or additional warnings would have changed his decision to prescribe Neurontin to Mr. Smith in ***March 2004***.

Though Plaintiff argues that Dr. Mackey would have "changed the way he treated Mr. Smith" by warning him about potential side effects (Pl. Opp. at 3, 7), she does not dispute the utter lack of evidence that Dr. Mackey would have changed his prescription decision. This is fatal to all of Plaintiff's claims. Numerous courts, including a Tennessee appellate court, have held that judgment as a matter of law was required because – as in this case – there was no competent evidence that different or additional warnings would have changed the doctor's decision to prescribe the defendants' drug or medical device. *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. App. 2001) (affirming summary judgment where plaintiffs failed to present evidence "that [doctors'] decisions [to use defendants' device] were influenced by any representation which the defendants made or failed to make"); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 95 (Tex. Ct. App. 2000) (reversing denial of judgment as a matter of

law because plaintiff failed to present evidence "that a proper warning [to the physician] would have changed the decision of the [physician] to prescribe the product"); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812, 812 (5th Cir. 1992) (affirming judgment as a matter of law where plaintiff failed to present evidence "that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff"); *Nix v. SmithKline Beecham Corp.*, No. CV-06-43-PHX-SMM, 2007 WL 2526402, at *3 (D. Ariz. Sept. 5, 2007) (granting summary judgment where plaintiff failed to show that additional warnings would have changed prescription decision).

Plaintiff does not address or attempt to distinguish any of these authorities, and the single case she does cite is inapposite. In *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960 (E.D. Wis. 2009), the court applied Wisconsin law, noted that Wisconsin has not adopted the learned intermediary doctrine, and thus determined that it "need not and will not apply the 'learned intermediary' doctrine in this case." *Id.* at 968. Unlike Wisconsin, the Tennessee Supreme Court has adopted the learned intermediary doctrine. *See, e.g., Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (granting summary judgment in favor of drug manufacturer after determining that the learned intermediary doctrine applied). Though the *Forst* court remarked that the learned intermediary doctrine would not have required summary judgment, *see Forst*, 602 F. Supp. 2d at 968, these remarks were pure *dicta* given the court's holding that the doctrine was not recognized under Wisconsin law. Plaintiff does not cite a single case in which the actual holding supports her position, nor does she discuss Pfizer's authorities in which the actual holdings support summary judgment.

Plaintiff merely argues that, if adequately warned, Dr. Mackey and Nurse Krancer might have given Mr. Smith unspecified warnings about potential side effects. But a plaintiff may only withstand summary judgment in such circumstances by presenting evidence – of which there is none here – that the patient, if warned, would not have taken the medication.[11] Plaintiff presents

[11] *See Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1313-14 & n.23 (D. Kan. 2008) (holding that testimony that physician would have monitored the patient more closely and warned *(cont'd)*

no such evidence, nor can she. It is undisputed that Mr. Smith did not comply with his doctors' instructions regarding Neurontin: he did not fill his May 2003 Neurontin prescription, did not take any of the Neurontin samples given to him by Nurse Krancer, and did not take his March 2004 Neurontin prescription as directed by Dr. Mackey. *See* Section I.A, *supra*. The notion that Mr. Smith would have refused to take Neurontin – even if it was still prescribed for him – based on unspecified warnings that Dr. Mackey or Nurse Krancer might have given is pure speculation and flatly inconsistent with his undisputed history of failing to follow his doctors' instructions. "Speculation about how this tragedy might have been avoided is absolutely understandable and perhaps inevitable, but plaintiffs cannot escape summary judgment based on speculation." *Vanderwerf*, 529 F. Supp. 2d at 1314.

Lacking any evidence that any warnings would have changed Mr. Smith's behavior, Plaintiff instead offers the bizarre and self-defeating argument that her inability to "establish that Mr. Smith took Neurontin or when he took the drug, even without an additional warning," somehow shows that additional warnings would have prevented him from taking Neurontin. (Pl. Opp. at 8.) The obvious flaw in this argument is that Plaintiff cannot prove cause in fact without, *inter alia*, presenting evidence ***both*** that Mr. Smith ingested Neurontin at a time temporally related to his suicide ***and*** that a different or additional warning would have prevented him from doing so. Plaintiff's failure to present evidence of ingestion does not support cause in fact, it negates it.

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the patient of risks did not bar summary judgment where plaintiff had no evidence that, given the additional monitoring and warning, the injury would have been avoided); *see also Spence v. Danek Med., Inc.*, No. 96C-1004, 1998 WL 665760, at *4 (Tenn. Cir. Ct. June 17, 1998) (affirming the propriety of summary judgment where a plaintiff "failed to carry his burden of establishing that the drug would not have been prescribed had an adequate warning been provided") (citing *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478 (E.D. Okla. 1997)).

II. All of Plaintiff's Claims Fail Because Plaintiff Cannot Establish Proximate Causation[12]

Even if Plaintiff could present evidence of cause in fact, which she cannot, her claims still fail because she cannot establish proximate cause. As discussed in Pfizer's opening brief, "Tennessee courts have . . . 'consistently recognized' that suicide properly constitutes an independent intervening cause in most wrongful death actions." *MacDermid v. Discover Fin. Servs.*, 488 F.3d 721, 736 (6th Cir. 2007) (quoting *Rains v. Bend of River*, 124 S.W.3d 580, 593 (Tenn. Ct. App. 2003)). There are only three exceptions to the rule that suicide breaks the chain of causation, and Plaintiff invokes only one of them: "where defendant's negligence causes 'delirium' or 'insanity' that results in self-destructive acts." *Id.*; *accord Rains*, 124 S.W.3d at 593-94.[13]

Plaintiff claims that the delirium/insanity exception applies because Dr. Trimble opines that Mr. Smith's suicide was "spontaneous and impulsive." (Pl. Opp. at 10.) But Dr. Trimble, who is "not a suicidologist" (Trimble Dep. (1/15/10 Cheffo Decl., Exh. 1) at 502:15-18), simply used the terms "spontaneous and impulsive" to express his view that Mr. Smith's suicide "came out of the blue" (*id.* at 551:21-25.) Even putting aside the implausibility of this view – given Mr.

[12] Contrary to Plaintiff's procedural arguments, this issue is properly before the Court. Pfizer is not seeking a "second bite at the apple." (Pl. Opp. at 9.) Pfizer is instead making an argument based on Tennessee law that, had it been raised in the MDL court, would have been deferred for this Court's consideration along all the other "questions of Tennessee law" that Judge Saris determined were "best left for the transferor court in Tennessee to resolve." *See In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 1629, [05-11515 Dkt. No. 10] at 2 (D. Mass. Aug. 14, 2009). Plaintiff is not prejudiced by the timing of this argument. Even if Pfizer were raising new arguments in the context of a reply brief or reconsideration motion – which it is not – "[t]he Court [could] either disregard the argument or allow [the opposing party] the opportunity to respond." *Smith v. Wynfield Dev. Co.*, 451 F. Supp. 2d 1327, 1339 (N.D. Ga. 2006). Plaintiff has had that opportunity. The issue has been fully briefed by both parties. No purpose would be served by proceeding to trial without first addressing a dispositive issue of Tennessee law that the MDL court would not have addressed even if it had been raised sooner.

[13] The other two exceptions, which Plaintiff does not invoke, are "where defendant is the decedent's custodian, and defendant knows or has reason to know that the decedent might engage in self-destructive acts" and "where defendant and decedent have a legally recognized 'special relationship,' such as physician-patient relationship, and defendant knows or has reason to know that the decedent might engage in self-destructive acts." *See MacDermid*, 488 F.3d at 736 (rejecting applicability of these exceptions).

Smith's long history of chronic pain and suicidal ideation – it does not remotely support application of the delirium/insanity exception. That exception requires evidence that the decedent was "'bereft of reason,'" such that he "'did not know or understand the nature of [his] act.'" *MacDermid*, 488 F.3d at 737 (quoting *Lancaster v. Montesi*, 216 Tenn. 50, 53, 390 S.W.2d 217, 219 (Tenn. 1965)). Suicide involving a "*moderately intelligent power of choice*" is an independent intervening cause "even [where] the choice is determined by a disordered mind." *Id.* (emphasis in original) (quoting *Jones v. Stewart*, 183 Tenn. 176, 179, 191 S.W.2d 439, 440 (1946)).

In *MacDermid*, the decedent's husband testified that he was "shocked and surprised by his wife's suicide." 488 F.3d at 726. In other words, her suicide "came out of the blue." (Trimble Dep. (1/15/10 Cheffo Decl., Exh. 1) at 551:21-25.) Nevertheless, there was no medical evidence that the decedent was incapable of a "moderately intelligent power of choice," and to the contrary, she had left a left a "cogen[t] . . . suicide letter" and had demonstrated "lucidity" during a recent doctor's appointment. *MacDermid*, 488 F.3d at 738. Accordingly, the Sixth Circuit held as a matter of law that the delirium/insanity exception did not apply. *See id.*

Likewise, none of Plaintiff's experts have even suggested that Mr. Smith's suicide did not spring from even a "moderately intelligent power of choice." To the contrary, the undisputed facts clearly confirm that Mr. Smith understood the nature of his act, given (i) his lucid, grammatically correct suicide note, which clearly articulated both his reasons and his desire for forgiveness, (ii) the fact that he locked the door and put plastic on the bed, and (iii) his remark about suicide a year before ingesting any Neurontin. Plaintiff's attempt to broadly construe the delirium/insanity exception ignores ample authority demonstrating that this exception is "extremely limited in application," and there is not "a single [Tennessee] case in which this particular exception was applied in a *plaintiff's* favor." *MacDermid*, 488 F.3d at 736-37.

Plaintiff further argues that Pfizer's authorities are all distinguishable because "none . . . involve a pharmaceutical company that has been accused of wrongfully selling a prescription drug that allegedly caused a patient who consumed the drug to commit suicide." (Pl. Opp. at 10.)

Plaintiff fails to explain how these allegations distinguish this case from authorities dismissing wrongful death claims despite conduct vastly more egregious than anything alleged here. *See, e.g.*, *Lancaster*, 216 Tenn. at 53, 390 S.W.2d at 219, 221 (decedent's suicide was independent, intervening cause even though defendant abused decedent sadistically and knew she was suicidal). As the Sixth Circuit put it, "[i]f the facts of . . . *Lancaster* do not [support proximate causation] . . . then neither do the facts in the instant case." *MacDermid*, 488 F.3d at 738.

Plaintiff also makes general foreseeability arguments that she does not even attempt to fit within any of the three narrow exceptions to the presumptive rule that suicide constitutes an independent, intervening cause in wrongful death cases. These arguments must be rejected under controlling Sixth Circuit law. As the Sixth Circuit has explained, Tennessee's framework for analyzing suicide as intervening cause is not based on fact issues regarding foreseeability, but on policy determinations establishing a "'boundary of legal liability,'" *MacDermid*, 488 F.3d at 736 (citation omitted), "'based on considerations of logic, common sense, policy, precedent and our more or less inadequately expressed ideas of what justice demands,'" *id.* (quoting *White v. Lawrence*, 975 S.W.2d 525, 529 (Tenn. 1998)).

No authority supports Plaintiff's attempt to use general foreseeability arguments to do an end-run around Tennessee's settled framework, comprising a presumptive rule subject to narrow (and inapplicable) exceptions. Instead, Plaintiff relies upon decisions from other states that did not apply Tennessee law and thus have no bearing on this case.[14] Plaintiff also relies on flawed

[14] (*See* Pl. Opp. at 11 (citing *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008) (applying New Mexico law) and *Stupak v. Hoffman-La Roche, Inc.*, 287 F. Supp. 2d 968 (E.D. Wis. 2003) (applying Wisconsin law)).) In *Rimbert*, the decedent did not simply commit suicide, but also shot his wife (and dog) in a "homicide/suicide," 577 F. Supp. 2d at 1182-83, and the drug's alleged side-effects at issue were not just suicide, but also "delusions" and "psychosis," *id.* at 1181, 1186, 1234. The *Rimbert* court appeared to apply some variant of the delirium/insanity exception, *id.* at 1234-35, albeit much more broadly than would be permitted under Tennessee law. Likewise, the *Stupak* plaintiffs alleged that the defendant's drug caused "psychosis" and caused the decedent to commit suicide based on "an uncontrollable impulse and without conscious volition." 287 F. Supp. 2d at 970, 975. These allegations, which were taken as true under FRCP 12(b)(6), *see id.* at 970, could at least arguably fit some local variant of Tennessee's delirium/insanity exception. But as discussed above, no evidence of delirium or insanity has been presented here.

interpretations of Tennessee state court cases that are contrary to the Sixth Circuit's interpretation of those same cases. Thus, Plaintiff cites *Rains* and *White* in support of general foreseeability arguments untethered to any of the three recognized exceptions. (Pl. Opp. at 10, 11-12.) In *MacDermid*, the Sixth Circuit not only construed both of these cases differently than Plaintiff does, but explicitly cited *Rains* as the principal authority for its holding that "suicide properly constitutes an independent intervening cause in most wrongful death actions" except where one of "three exceptions to this general rule" applies. *MacDermid*, 488 F.3d at 736 (quoting *Rains*, 124 S.W.3d at 593-94). At the risk of stating the obvious, the Sixth Circuit's interpretations of these cases are controlling, whereas Plaintiff's contrary interpretations are entitled to no weight.[15]

Even if the Sixth Circuit had not already rejected them, Plaintiff's interpretations of *Rains* and *White* would be meritless. In *Rains*, the court ***reversed*** the lower court's ***denial*** of summary judgment based on suicide as intervening cause, 124 S.W.3d at 587, thus flatly refuting Plaintiff's interpretation of *Rains* as holding that these issues are inherently factual. (*See* Pl. Opp. at 10.) And while *White* upheld the trial court's denial of summary judgment, *see* 975 S.W.2d at 532, its facts are easily distinguishable. The defendant in *White* was the decedent's doctor, knew that the decedent "suffered from severe depression," and "felt that [he] was a 'likely candidate' for suicide." *Id.* at 527. These facts fit squarely within the recognized exception that applies "where defendant and decedent have a legally recognized 'special relationship,' such as physician-patient relationship, and defendant knows or has reason to know that the decedent might engage in self-destructive acts." *MacDermid*, 488 F.3d at 736.

Plaintiff claims that this case is "similar" to *White* (Pl. Opp. at 12), but she does not invoke the exception that applied in that case or even attempt to show that it applies here. Nor can she. Unlike in *White*, there was no "physician-patient relationship" or any other "special

[15] *See, e.g., Combs v. Int'l Ins. Co.*, 163 F. Supp. 2d 686, 691 (E.D. Ky. 2001) (stating that district courts are bound by Sixth Circuit's interpretation of state substantive law), *aff'd*, 354 F.3d 568 (6th Cir. 2004).

relationship" between Pfizer and Mr. Smith, *MacDermid*, 488 F.3d at 736, and there is no evidence that Pfizer even knew who Mr. Smith was, let alone that he was "depress[ed]" or a "'likely candidate' for suicide," *White*, 975 S.W.2d at 527. Instead, Plaintiff's claim is that Pfizer marketed an FDA-approved medication alleged to cause suicidal ideation – a claim as to which there is considerable, legitimate dispute. No authority supports Plaintiff's attempt to use these allegations as the basis for an entirely new exception to the settled Tennessee and Sixth Circuit principle that suicide is an independent, intervening cause.

III. Plaintiff's Implied Warranty Claims Fail as a Matter of Law

As set forth in Pfizer's opening brief, Plaintiff cannot recover under a theory of implied warranty because it is undisputed that she failed to provide any notice of the alleged breach, which is a condition precedent to filing suit. *See* Tenn. Code Ann. § 47-2-607(3)(a). Plaintiff claims that "commenc[ing]" "this wrongful death lawsuit" within a purportedly "reasonable time" after Mr. Smith's suicide provided the required notice. (Pl. Opp. at 13.) She misses the point entirely. The purpose of the statutory notice requirement is to give sellers the opportunity to settle the dispute ***prior to litigation***. *See* U.C.C. § 2-607 cmt. 4 (2009) ("[N]otification . . . opens the way for normal settlement through negotiation."); *see also Parker v. Bell Ford, Inc.*, 425 So. 2d 1101, 1103 (Ala. 1983) (pre-suit notice allows vendor to "suggest opportunities for cure"). Notice received via summons and complaint is unreasonable as a matter of law. *See Friedman v. Georgia Showcase Co.*, 27 Tenn. App. 574, 183 S.W.2d 9 (1944) (holding that statutory notice requirement was not met, and contract claim "cannot be maintained," where plaintiff did not give "notice of his intention to claim a breach . . . until the pleadings were filed") (construing Uniform Sales Act provision); *see also, e.g., Williams v. Mozark Fire Extinguisher Co.*, 888 S.W.2d 303, 305-06 (Ark. 1994) (holding that "the giving of notice must be alleged in the complaint to state [an implied warranty] cause of action" and that "the notice must be more than a complaint"). Plaintiff cites no authority supporting her nonsensical argument that filing a lawsuit satisfies the requirement for pre-suit notice.

In addition, Plaintiff cannot prevail on her claim for breach of the implied warranty of fitness, because she cannot prove that Mr. Smith or Dr. Mackey actually relied on Pfizer's skill and judgment in purchasing Neurontin. Tenn. Code Ann. § 47-2-315; *see also* U.C.C. § 2-315, cmt. 1 ("The buyer, of course must actually be relying on the seller."); *Travelers Indem. Co. v. Indus. Paper & Packaging Corp.*, No. 3:02-CV-491, 2006 WL 3864857, at *10 (E.D. Tenn. Dec. 18, 2006). Dr. Mackey's testimony that he "probably" read the Neurontin package insert "[a] long time ago" (Mackey Dep. (1/15/10 Cheffo Decl., Exh. 2) at 79:20-80:1) is not evidence that he relied on the label or on Pfizer's skill and judgment when he prescribed the drug to Mr. Smith. By definition, nothing on the product's label or product insert made any representations or warranties about off-label uses. Moreover, as discussed in Section I.C, *supra*, there is no evidence that different or additional warnings would have changed Dr. Mackey's prescription decision.

Plaintiff also cites an inadmissible hearsay statement purportedly made by Mr. Smith to the effect that he had "gone online" looking for information about Neurontin. (5/19/04 Letter from Dr. Wood [MDL 1679-2].) This hearsay statement is inadmissible for the reasons discussed above. *See* pp. 6-7 & ftns. 7-9, *supra*. Even if not hearsay, it would be irrelevant. The issue for implied warranty purposes is whether Mr. Smith relied on any warranties when he ***purchased*** Neurontin, not when he allegedly ***consumed*** it post-sale.[16] And even if relevant, it would not raise fact issues for trial. Mr. Smith's purported statement that he read unspecified information about Neurontin "online" does not even indicate that Mr. Smith saw any statements made by Pfizer. Nor is there any evidence that Mr. Smith took Neurontin at any time after going "online." Plaintiff's argument that Mr. Smith must have seen and "relied on information disseminated by Defendants," and that he "continued to take Neurontin to treat his pain based

[16] "[T]here can be no recovery [under an implied warranty theory] unless it is shown that the goods purchased did not measure up to the requirements of such implied warranty ***at the time such goods passed from the seller to the purchaser***." *Leach v. Wiles*, 58 Tenn. App. 286, 305, 429 S.W.2d 823, 832 (1968) (emphasis added); *accord Hollingsworth v. Queen Carpet, Inc.*, 827 S.W.2d 306, 309 (Tenn. Ct. App. 1991).

upon his reliance upon such information" (Pl. Opp. at 14), is a purely conclusory assertion unsupported by any evidence.

IV. Plaintiff's Fraudulent Concealment Claims Fail For Additional Reasons

Plaintiff's opposition brief is completely unresponsive to Pfizer's arguments regarding her fraudulent concealment claim. Plaintiff's arguments overwhelmingly concern her already-dismissed claims of "***affirmative fraudulent promotion***" and her already-dismissed claims of fraudulent concealment based on alleged omissions in a national marketing campaign. (Pl. Opp. at 18 (emphasis in original); *see also id.* at 14-20.) Likewise, Plaintiff reiterates her already-rejected fraud-on-the-market theory that Mr. Smith's prescribing doctors were "influenced, albeit indirectly," by alleged misrepresentations or omissions to the medical community at large. (*Id.* at 19; *see also id.* at 20.)

Three months after Plaintiff made these exact same arguments, the MDL court dismissed "all [Plaintiff's] claims of affirmative fraudulent misrepresentations." *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009); *see also In re Neurontin Mktg.*, [05-11515 Dkt. No. 10] at 2. The MDL court also dismissed Plaintiff's fraudulent concealment claims to the extent they are "premised on . . . fraudulent omissions in the national advertising and marketing campaign," as this would require an untenable fraud-on-the-market theory of reliance. *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 618 F. Supp. 2d at 114. Plaintiff simply ignores the MDL court's order dismissing the bulk of her fraud claims, makes the exact same arguments she made before these claims were dismissed, and makes no attempt to identify any evidence pertaining to what little remains of her fraud claims.[17]

To the extent that any of Plaintiff's evidence or arguments pertain to any remaining fraudulent concealment claims, those claims cannot survive summary judgment. As set forth in

[17] Pfizer will not burden the Court by reiterating its prior responses to the majority of Plaintiff's arguments, since they are irrelevant to this case in its current posture. Instead, Pfizer incorporates by reference its prior responses to those same arguments. (Defs. Reply Mem. Supp. Summ. J. [MDL 1708] at 13-20.)

Pfizer's opening brief, the Tennessee Supreme Court has held that a party commits fraudulent concealment only when it "has a duty to disclose a known fact or condition [but] fails to do so, and another party reasonably relies upon the resulting misrepresentation, thereby suffering injury." *Chrisman v. Hill Home Dev., Inc.*, 978 S.W.2d 535, 538-39 (Tenn. 1998) (citations omitted). Under Tennessee law, "[t]he duty to disclose arises in three distinct circumstances: (1) [w]here there is a previous definite fiduciary relation between the parties, (2) [w]here it appears one or each of the parties to the contract expressly reposes a trust and confidence in the other, and (3) [w]here the contract or transaction is intrinsically fiduciary and calls for perfect good faith." *Shah v. Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003) (internal quotation marks omitted) (citations omitted); *accord Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 721 (E.D. Tenn. 2001). "Clearly, none of those circumstances are present here," and Plaintiff is thus unable to establish a duty. *Morgan*, 165 F. Supp. at 722 (granting summary judgment to beryllium manufacturer on fraudulent concealment claims for lack of duty to disclose); *see also McConkey v. McGhan Med. Corp.*, 144 F. Supp. 2d 958, 965-66 (E.D. Tenn. 2000) (granting summary judgment to breast implant manufacturer on fraud claims for lack of duty to disclose).[18]

Plaintiff ignores these authorities. While Plaintiff argues generically that "concealment or suppression of the truth ***can*** constitute fraud" under Tennessee law (Pl. Opp. at 14 (emphasis added)), she makes no attempt to show that the facts of this case fit any of the "three distinct circumstances" in which a duty to disclose can arise, *Shah*, 338 F.3d at 571. Absent a duty to disclose, of which there is no evidence here, Plaintiff cannot make out an essential element of her fraudulent concealment claims, and Pfizer is entitled to judgment as a matter of law.

CONCLUSION

For the foregoing reasons, this Court should grant Pfizer's motion for summary judgment, dismissing Plaintiff's claims in their entirety.

[18] Neither can Plaintiff base her state-law fraudulent concealment claim on a federal duty to disclose information to the FDA, because such claims are barred by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), which held that fraud-on-the-FDA claims are preempted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 15th day of January 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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